

Docket No. 3/400-5-C5

**REMARKS**

Claims 1-6 have been canceled. New claims 7-18 have been added. Support for new claims 7-18 is found throughout the specification. Support for new claim 7 and claims 8-17 dependent thereon can be found throughout the specification, *inter alia*, Example 1, page 18, in particular, lines 23-24. Support for new claim 18 can be found throughout the specification, *inter alia*, at page 3, lines 31-32. No new matter is added.

**Section 112 Rejections**

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph for lack of enablement.

The Examiner alleges that it is not clear what Applicants used in the vaccine preparation nor what dermatophytes gave rise to the vaccine protection shown in Table 10. The Examiner also contends that there does not appear to be support or enablement for a vaccine consisting of just one dermatophyte, *T. verrucosum*. The Examiner also points out that Applicants' composition does not recite a carrier or adjuvant and contends that according to Gidding *et al.*, Can. Vet. J., 1995, adjuvants are important in stimulating the cellular branch of the immune system and that the cellular branch is crucial for protection.

Applicants respectfully disagree. Applicants point out that claims 1-6 have been canceled. New claim 7 (and claims 8-17 dependent thereon) are directed to a dermatomycosis vaccine comprising inactivated dermatophytes, wherein the inactivated dermatophytes consist of *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), and one or more inactivated dermatophytes selected from the group consisting of *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporum gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274).

Docket No. 3/400-5-C5

Applicants have provided sufficient guidance in the specification which, when combined with the routine methods commonly known in the art, render routine the preparation and use of the claimed vaccines.

The Examiner's attention is directed to the instant specification at page 4, lines 10-15 and Example 1, pages 18-20, which discloses how to make the vaccine preparations. In particular, Example 1 describes taking 125 ml of each culture of the eight strains recited in claim 1 and mixing them together in a single container, inactivating the mixture, and bottling the resulting vaccine (page 18, lines 16-30). Alternatively, the "vaccine may be prepared by mixing together various combinations of the given strains" (page 18, lines 23-24), i.e., the combination of four or more strains as recited in claims 7-17.

Further, the specification describes immunizing the animals using the vaccine prepared in Example 1 to determine dosage to be given and the method of administration for prevention and treatment (page 18, line 33 and Table 8); the effectiveness of the vaccine in preventing disease (Example 2, page 21, and Table 9); and the effectiveness of the vaccine in treating infected animals (Example 3, page 21 and Table 10).

In addition, Applicants submit that the immunogenic response produced by immunization of an animal with a vaccine comprising a single inactivated strain, as described in Tables 1-7, establishes (results in) immunity to that strain.

Applicants respectfully direct the Examiner's attention to the Declaration of Dr. Igor Polyakov under 37 C.F.R. §1.132 ("the Declaration"). As stated in paragraph 5 of the Declaration, the vaccines of the present invention which are described in the Declaration were prepared essentially according to the method disclosed in the instant application. The minor, insubstantial differences between the method for preparing the vaccines disclosed in the above-identified application and the methods described in the Declaration are described in paragraph 6 of the Declaration. As is stated in paragraph 6 and demonstrated in paragraph 7 of the Declaration, such minor differences had no significant effect on the properties of the

Docket No. 3/400-5 US

vaccines. Further, all of the challenge experiments were performed in the absence of adjuvants (paragraph 5).

Applicants further direct the Examiner's attention to paragraphs 8-12 of the Declaration wherein production and efficacy of dermatomycosis vaccines comprising four and five fungal strains is described. Results of these experiments are presented in Table 1, Examples 2-6. The experiments and results in paragraphs 8-12 correspond to new claims 8, 11, 9, 10, and 14, respectively. Production and efficacy of dermatomycosis vaccines comprising a single fungal strain is described in paragraph 13 of the Declaration; results of these experiments are presented in Table 1, Example 7.

Applicants submit that as the nature of the invention is in the fields of immunology, animal health and vaccine, which are very highly developed, the state of the prior art is high, and the relative skill of those in the art is at a very high level, one would expect that one of skill in the art would easily be able to use the directions in the specification to combine the various fungal strains described to make and use the vaccines according to the invention.

Thus, Applicants submit that from the teachings of specification and the experiments and results described in the Declaration, the vaccines according to the invention are described in such a way as to enable one skilled in the art to make and/or use the invention. Applicants further submit that such activity results would have been both surprising and unexpected to one of ordinary skill in the art.

In light of the above amendments and remarks, it is submitted that the rejections based on Section 112, first paragraph for lack of enablement have been overcome.

#### **Double Patenting Rejection**

Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of co-pending Application No. 10/085,703.

Docket No. 3/400-5-CS

Applicants respectfully request that this rejection be addressed when the claims are found to be allowable as the subject matter of the claims may be amended during prosecution.

### Section 102 Rejections

#### **Paragraph 7 of the Office Action**

Claim 1 is rejected under 35 U.S.C. § 102(h) as being anticipated by Wawrzekiewicz *et al.*, 1991, Med. Weter., 47(7):317-320 ("Wawrzekiewicz *et al.*"). The Examiner alleges that Wawrzekiewicz *et al.* disclose an inactivated vaccine against trichophytosis and that the vaccine comprises inactivated *T. verrucosum*.

In complete contrast, the vaccines of the invention as presently claimed comprise inactivated dermatophytes consisting of *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), and one or more inactivated dermatophytes selected from the group consisting of *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporum gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274).

Thus, this rejection under section 102 has been overcome and must be withdrawn.

#### **Paragraph 8 of the Office Action**

Claim 1 is rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,277,904 by Picr ("the '904 Patent").

Docket No. 3/400-5-CS

According to the Examiner, the '904 Patent discloses a vaccine (and the preparation of a vaccine) for the prophylaxis of dermatophyte infection in animals using *T. mentagrophytes*, *M. canis*, and *M. gypsum*.

In complete contrast, the vaccines of the invention as presently claimed comprise inactivated dermatophytes consisting of *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), and one or more inactivated dermatophytes selected from the group consisting of *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporum gypsum* Strain No. VKPGF-729/59 (accession No. DSM 7274).

Thus, this rejection under section 102 has been overcome and must be withdrawn.

#### Paragraph 9 of the Office Action

Claims 1, 3 and 4 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 5,453,273 by Werner *et al.* ("the '273 Patent"), U.S. Patent 6,132,733 by Werner *et al.* ("the '733 Patent"), U.S. Patent 6,428,789 by Strobel *et al.* ("the '789 Patent") or U.S. Patent 6,723,328 by Strobel *et al.* ("the '328 Patent").

According to the Examiner, the '328 Patent discloses a ringworm vaccine comprising inactivated (formaldehyde-killed) *M. canis*, *M. gypsum*, or *T. mentagrophytes*. The Examiner further states that the '328 Patent discloses a list of dermatophytes and the hosts that they infect.

Applicants respectfully submit that the '328 Patent describes and claims a *method* of producing a ringworm vaccine comprising growing at least one dermatophyte selected from

Docket No. 3/400-5-C5

the group consisting of *M. canis*, *M. gypsum* and *T. mentagrophytes*. Further, the '328 Patent merely provides a list of dermatophytes which in no way enables vaccines comprising combinations other than those described in the Examples, i.e., comprising *M. canis* alone or in combination with *M. gypsum* and/or *T. mentagrophytes*.

Applicants respectfully submit that the '789 Patent describes and claims a method of administering a ringworm vaccine comprising *M. canis* alone or in combination with *M. gypsum* and/or *T. mentagrophytes*. Further, the '789 Patent merely provides a list of dermatophytes which in no way enables vaccines comprising combinations other than those described in the Examples, i.e., comprising *M. canis* alone or in combination with *M. gypsum* and/or *T. mentagrophytes*.

Applicants respectfully submit that the '273 Patent and the '733 Patent describe and claim a ringworm vaccine comprising *M. canis* alone or in combination with *M. gypsum* and/or *T. mentagrophytes*. Further, the '789 Patent merely provides a list of dermatophytes which in no way enables vaccines comprising combinations other than those described in the Examples, i.e., comprising *M. canis* alone or in combination with *M. gypsum* and/or *T. mentagrophytes*.

In complete contrast, the vaccines of the invention as presently claimed comprise inactivated dermatophytes consisting of *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), and one or more inactivated dermatophytes selected from the group consisting of *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporum gypsum* Strain No. VKPGF-729/59 (accession No. DSM 7274).

Thus, this rejection under section 102 has been overcome and must be withdrawn.

Docket No. 3/400-5-CS

**Paragraph 10 of the Office Action**

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,368,191 by Sarkisov *et al.* ("the '191 Patent") or Woloszyn *et al.*, 1983, Med. Weter., 39(7):387-391 (Abstract only) ("Woloszyn *et al.*").

According to the Examiner, Woloszyn *et al.*, for example, disclose inactivated strains of *T. mentagrophytes*.

Applicants respectfully submit that the '191 Patent describes and claims a vaccine (and method of use and method for preparing said vaccine) for the prophylaxis and treatment of trichophytosis comprising *T. mentagrophytes*. Indeed, the "purpose of the aforesaid invention was to provide a strain of *Trichophyton gypseum* (*T. mentagrophytes*) which would be harmless for human beings and animals..." (col. 3, lines 63-66).

In complete contrast, the vaccines of the invention as presently claimed comprise inactivated dermatophytes consisting of *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), and one or more inactivated dermatophytes selected from the group consisting of *Trichophyton equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *Microsporum canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *Microsporum canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporum canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporum gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274).

Thus, this rejection under section 102 has been overcome and must be withdrawn.

In view of the above, the cited references cannot and do not anticipate the claims of the present invention, neither alone nor in combination, thus a rejection based on anticipation has

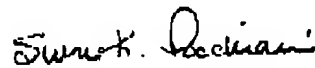
Docket No. 3/400-5-C5

not been made. Accordingly, withdrawal of the rejections based on Section 102 is respectfully requested.

### CONCLUSION

Applicants believe the present application is in condition for allowance, early notification of which is respectfully requested. If the Examiner has any questions or matters to be resolved in the present application, the Examiner is earnestly solicited to call the undersigned attorney.

Respectfully submitted,



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